

### **Arguments/ Remarks**

Claims 108-115, 123, 131-136 are pending. Claims 112-113, 115, 125-130 have been withdrawn in light of the prior issued restriction requirement. Claims 1-107 and 116-122, 124 have been cancelled. Accordingly, claims 108-111, 114, 123, 131-136 are presently pending and under Examination. All claims stand free of the art.

Applicants have previously elected, for purposes of initial Examination, the hybridoma species 1F2 having ATCC accession no. PTA-5959. Applicants prior-filed Replay to the Official Action of November 30, 2007, provided a Verified Statement of co-inventor Maria Concetta Veri establishing the facts of this Deposit.

Applicants have requested rejoinder of the withdrawn claims and consideration of the Allowability of the full scope of the presented claims. In order to advance prosecution of such scope, Applicants herewith submit a Verified Statement of co-inventor Maria Concetta Veri establishing the facts of the deposits of the four additional clones recited in the claims:

1. Clone 1D5 having ATCC Accession No. PTA-5958;
2. Clone 2E1 having ATCC Accession No. PTA-5961;
3. Clone 2H9 having ATCC Accession No. PTA-5962; and
4. Clone 2D11 having ATCC Accession No. PTA-5960.

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. §121. The Application is believed to be in condition for further Examination and early notice of favorable action is respectfully requested.

In Re Patent Appln. of  
Scott Koenig and Marie Concetta Veri  
Serial No. 10/0643,857

Reply to the Official Action of November 30, 2007  
Page 3

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicants encourage the Examiner to contact the undersigned.

Respectfully Submitted,

Date: **March 4, 2008**

Edell, Shapiro & Finn, LLC  
1901 Research Boulevard, Suite 400  
Rockville, MD 20850  
Telephone: (301) 424-3640  
Facsimile: (301) 762-4056

**/Jeffrey I. Auerbach/**  
Jeffrey I. Auerbach  
Registration No. 32,680  
Attorney for Assignee

Customer No. **66522**

# In The United States Patent and Trademark Office

In re application of:  
*Koenig, Scott et al.*

Appl. No. 10/643,857

Filed: August 14, 2003

For: **FcγRIIB-Specific Antibodies  
and Methods of Use Thereof**

Art Unit: 1644

Examiner: **Dahle, Chun Wu**

Atty. Docket: **1301.0019C**

Confirmation No.: 1191

## Second Verified Statement of Maria Concetta Veri

Filed via EFS-Web  
Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Maria Concetta Veri, hereby declare:

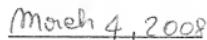
1. I am a co-inventor of the invention claimed in the above-described patent application, and have personal knowledge of the matters related in this Declaration.
2. On February 28, 2008, I submitted a Verified Statement relating to the Deposit of the hybridoma cell lines **1F2** (ATCC Accession No. PTA-5959). I make this Second Verified Statement to address the Deposits of the hybridoma cell lines: **1D5, 2D11, 2E1** and **2H9**, which are described in the above-identified patent application.
3. Each of the hybridoma cell lines: **1D5, 2D11, 2E1** and **2H9**, which are described in the above-identified patent application were produced prior to the filing date of the above-identified patent application.

4. On May 4, 2004, I deposited each of the hybridoma cell lines **1D5**, **2D11**, **2E1** and **2H9** with the American Type Culture Collection (ATCC) under the terms of the Budapest Treaty. I have enclosed a copy of the original Deposit Forms as evidence of the May 4, 2004 deposit. The deposited hybridomas were found to be viable by the ATCC and were accorded ATCC Accession Nos.: PTA-5958 (cell line **1D5**); PTA-5960 (cell line **2D11**); PTA-5961 (cell line **2E1**); and PTA-5962 (cell line **2H9**). I enclose the certificate of viability for these cell lines and for PTA-5959 (cell line **1F2**).
5. From a time prior to the filing date of the above-identified patent application to May 4, 2004, each of the hybridoma cell lines **1D5**, **2D11**, **2E1** and **2H9** were kept under my personal supervision and control in a liquid nitrogen freezer. To my knowledge no other person accessed these cell lines during this period.
6. Each of the hybridoma cell lines: **1D5**, **2D11**, **2E1** and **2H9**, which are described in the above-identified patent application is the same cell line that was deposited with the American Type Culture Collection on May 4, 2004 and accorded ATCC Accession Nos.: PTA-5958 (cell line **1D5**); PTA-5960 (cell line **2D11**); PTA-5961 (cell line **2E1**); and PTA-5962 (cell line **2H9**).
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of  
the application or any patent issued thereon.



**Maria Concetta Veri**



**Date**



**BUDAPEST TREATY DEPOSIT FORM (BP/1)**

**American Type Culture Collection**  
P.O. Box 1549  
Manassas, VA 20108

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE  
INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF A PATENT PROCEDURE

ALL QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED.

1. Name of deposit. Please mark the appropriate box and provide the information requested for the material:

- Microorganism – the complete scientific name including genus and species plus the source of the material
- Virus – the name, whether plant or animal, and source including geographic location
- Cell line – the species and tissue of origin, geographical source of isolation, and any known associated hazards (HIV, EBV, etc.)
- Genetic material – the name of organism from which vector, clone or library is derived, the source of the DNA insert identified by species (e.g., human, mouse) or scientific name, the name of gene, and the identity of the host organism
- Consortia or mixed culture – the identity of each component of the mixture
- Seeds, embryos, Insect eggs, etc. – the common name, the scientific name of the source of the deposit, and geographical source

HYBRIDOMA FCB R1A TRANSGENIC MICE WERE IMMUNIZED WITH MAMMALIAN EXPRESSED EXTRACELLULAR PORTION OF FGFRIIb. LYMPHOCYTES FROM THE IMMUNIZED MICE WERE FUSED WITH HL-1 MYOMA CELLS TO IMMORTALIZE THE

2. Strain designation\* (i.e., number, symbols, etc.) 1D5  
 \*The strain designation must correspond with the vial labels.

3. Is this an original deposit under the Budapest Treaty?  Yes  No

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty?  
 Yes  No  
 If yes, please indicate ATCC designation. \_\_\_\_\_

5. Is this deposit a mixture of microorganisms or cells?  Yes  No  
 If yes, please describe: \_\_\_\_\_

6. Provide details necessary to cultivate, test for viability and store the deposit. If a mixture, provide description of components and a method to check for presence. If a plasmid, provide name of host and antibiotic resistance.  
DULBECCO'S MODIFIED EAGLE MEDIUM SUPPLEMENTED WITH 15% FETAL CALF SERUM, 2MM GLUTAMINE AND 50UG/ML GENTAMICIN. CELLS HAVE BEEN FROZEN (10. 10<sup>6</sup> CELLS/1ML) IN FETAL CALF SERUM CONTAINING 10% DMSO AND PLACED IN LIQUID NITROGEN.

7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).  
ANHCF-1 CELLS.

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics?  Yes  No  
If yes, please list the antibiotics: GENTAMICIN (so, IgM)

b. If deposit is a hybridoma, what is the isotype of the antibody produced? mucine IgG1

8. Safety: Is this strain hazardous to humans? NO Animals? NO Plants? NO

8. Safety: Is this strain hazardous to humans? NO Animals? NO Plants? NO

If yes, what is the recommended biosafety level for working with this strain? \_\_\_\_\_  
(Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. HHS Publication No. (CDC) 93-8395. U.S. Department of Health and Human Services, Centers for Disease Control, Washington, DC; U.S. Government Printing Office; 1999. The entire text is available online at [www.cdc.gov/od/biotech/biosfty/bm4/bm4.htm](http://www.cdc.gov/od/biotech/biosfty/bm4/bm4.htm).)

## 9. Regulatory Compliance:

a. Was the material derived from a human?  Yes  No  
If yes, was an IRB-approved consent form (human subjects) obtained?  Yes  No

b. Was this material obtained from wildlife?  Yes  No  
If yes, please indicate genus and species and whether wild or captive bred. \_\_\_\_\_

c. Is work performed at your facility with exotic viruses affecting livestock and avian species?  Yes  No

d. Identify any reagents of animal origin used to cultivate this organism/cell line (serum, growth factors, trypsin, etc.) and manufacturer, if known: FETAL BOVINE SERUM (CERTIFIED - ORIGIN: UNITED STATES. MYCOPLASMA, VIRUS, BACTERIOPHAGE AND ENDOTOXIN TESTED (IN VITROGEN CORPORATION))

## 10. Availability:

Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent Patent Office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered:

a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued.  Yes  No

b. As of the date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requesters that satisfy Patent Offices in countries not signatory to the Budapest Treaty?  Yes  No  
If "yes," please state which countries: \_\_\_\_\_

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution. After a U.S. Patent issues and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office (USPTO) Rules and Regulations (37 CFR 1.808 (a)(2)).

## 11. Notification: ATCC will notify you of your ATCC number after viability of the deposit has been confirmed.

Name of individual to notify: Joseph E. Panigot  
Fax 301-251-5321 Phone: 301-354-0686 E-mail: panigot\_j@macrogenics.com

## 12. Payment by check or credit card (MasterCard, VISA or American Express) must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts purchase orders for the exact amount.

Purchase Order No. \_\_\_\_\_

Check No. \_\_\_\_\_

Credit Card number. \_\_\_\_\_

 MasterCard  VISA  American Express

Exp. Date: \_\_\_\_\_

Name shown on card: \_\_\_\_\_ (Please print clearly or type)

Signature of card holder: \_\_\_\_\_

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX FOR ALL DEPOSITS:

Contact Name: Marilyn MaracicBilling Address: Jones Day, 222 E. 41st StreetNew York, NY 10017-6702Phone: (212) 790-6417 Fax (212) 869-9741Do you have a current ATCC account number?  Yes  NoIf Yes: ATCC Account Number = 178147If No: To apply for an account with ATCC, please complete a New Account Application located on our Web site ([www.atcc.org](http://www.atcc.org)) and return it with supporting documentation to ATCC for approval.

13. Name, address, phone and fax number of your Attorney of Record.

Geroldine F. Baldwin Esq  
Jones Day 222 E. 41st Street  
New York, NY 10017-6022 (Ref. Docket or Case No. 111B3-013-999)

14. MUST BE COMPLETED. Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institution, and not an individual.)

MacroGenics, Inc.

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Joseph E. Paigot Joseph E. Paigot 5/4/04  
 Printed Name Signature Date

Address MacroGenics, Inc., 1500 East Gate Drive, Rockville, MD 20850

Phone: (301) 354-0686 Fax (301) 351-5321 E-mail: paigotj@macrogenics.com

#### SHIPPING INFORMATION

BEFORE SHIPPING, PLEASE CONTACT THE ATCC PATENT DEPOSITORY FOR SHIPMENT ADVICE:

Fax: (703) 365-2745  
 E-mail: PatentDeposit@atcc.org

#### SHIPPING NOTICE:

The depositor is ultimately responsible for the shipment of deposits to ATCC and compliance with all applicable government regulations for the packaging and movement of the material. The depositor shall indemnify ATCC, to the extent permitted by law, against claims resulting from the violation of applicable government regulations caused by the depositor's shipment of deposits to ATCC.

#### STORAGE & FEES

Storage: Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

Fees: All fees are subject to change. For current fees and other information, check our Web site at [www.atcc.org](http://www.atcc.org) or request a quotation of fees by e-mail at [PatentDeposit@atcc.org](mailto:PatentDeposit@atcc.org) or fax (703) 365-2745.

ATCC USE ONLY: ATCC DESIGNATION \_\_\_\_\_ REC'D \_\_\_\_\_ V.T. RESULT \_\_\_\_\_

ATCC® is a registered trademark of the American Type Culture Collection.



# BUDAPEST TREATY DEPOSIT FORM (BP/1)

American Type Culture Collection  
P.O. Box 1549  
Manassas, VA 20108

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF A PATENT PROCEDURE

ALL QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED.

1. Name of deposit. Please mark the appropriate box and provide the information requested for the material:

Microorganism – the complete scientific name including genus and species plus the source of the material  
 Virus – the name, whether plant or animal, and source including geographic location  
 Cell line – the species and tissue of origin, geographical source of isolation, and any known associated hazards (HIV, EBV, etc.)  
 Genetic material – the name of organism from which vector, clone or library is derived, the source of the DNA insert identified by species (e.g., human, mouse) or scientific name, the name of gene, and the identity of the host organism  
 Consortium or mixed culture – the identity of each component of the mixture  
 Seeds, embryos, insect eggs, etc. – the common name, the scientific name of the source of the deposit, and geographical

SOURCE  
HYBRIDOMA. FOLLICULAR TRANSGENIC MICE WERE IMMUNIZED WITH MAMMALIAN EXPRESSED EXTRACELLULAR, PORTION OF A FcRIB. LYMPHOCYTES FROM THE IMMUNIZED MICE WERE FUSED WITH H-1 MYELOMA CELLS TO IMMORTALIZE

2. Strain designation\* (i.e., number, symbols, etc.) 2D11

\*The strain designation must correspond with the vial labels.

3. Is this an original deposit under the Budapest Treaty?  Yes  No

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty?

Yes  No  
 If yes, please indicate ATCC designation.

5. Is this deposit a mixture of microorganisms or cells?  Yes  No  
 If yes, please describe:

6. Provide details necessary to cultivate, test for viability and store the deposit. If a mixture, provide description of components and a method to check for presence. If a plasmid, provide name of host and antibiotic resistance.

DULBECCO'S MODIFIED EAGLE MEDIUM SUPPLEMENTED WITH 15% FETAL CALF SERUM, 2mM GLUTAMINE AND 50μg/ml GENTAMICIN. CELLS HAVE BEEN FROZEN (1.0 · 10<sup>6</sup> cells/vial) IN FETAL CALF SERUM CONTAINING 10% DMSO AND PLACED IN LIQUID NITROGEN.

7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).

ADHERENT CELLS

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics?  Yes  No  
 If yes, please list the antibiotics: GENTAMICIN (50μg/ml)

b. If deposit is a hybridoma, what is the isotype of the antibody produced? murine IgG1

8. Safety: Is this strain hazardous to humans? NO Animals? NO Plants? NO

If yes, what is the recommended biosafety level for working with this strain?

(Refer to *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. HHS Publication No. (CDC) 93-8395, U.S. Department of Health and Human Services, Centers for Disease Control, Washington, DC; U.S. Government Printing Office, 1999. The entire text is available online at [www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm).)

## 9. Regulatory Compliance:

a. Was the material derived from a human?  Yes  No  
 If yes, was an IRB-approved consent form (human subjects) obtained?  Yes  No

b. Was this material obtained from wildlife?  Yes  No  
 If yes, please indicate genus and species and whether wild or captive bred. \_\_\_\_\_

c. Is work performed at your facility with exotic viruses affecting livestock and avian species?  Yes  No

d. Identify any reagents of animal origin used to cultivate this organism/cell line (serum, growth factors, trypsin, etc.) and manufacturer, if known: FETAL BOVINE SERUM CERTIFIED ORIGIN: UNITED STATES  
Mycoplasma, Virus, Bacteriophage and Endotoxin Tested  
(CINVITROGEN CORPORATION).

## 10. Availability:

Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent Patent Office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered:

a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued.  Yes  No

b. As of the date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requesters that satisfy Patent Offices in countries not signatory to the Budapest Treaty?  Yes  No  
 If "yes," please state which countries: \_\_\_\_\_

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution. After a U.S. Patent issues and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office (USPTO) Rules and Regulations (37 CFR 1.808 (a)(2)).

## 11. Notification: ATCC will notify you of your ATCC number after viability of the deposit has been confirmed.

Name of individual to notify: Joseph E. Paniget  
 Fax 301-151-5321 Phone: 301-354-1686 E-mail: paniget@macrogenics.com

## 12. Payment by check or credit card (MasterCard, VISA or American Express) must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts purchase orders for the exact amount.

Purchase Order No. \_\_\_\_\_

Check No. \_\_\_\_\_

Credit Card number: \_\_\_\_\_

 MasterCard  VISA  American Express

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Name shown on card: \_\_\_\_\_ (Please print clearly or type)

Signature of card holder: \_\_\_\_\_

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX FOR ALL DEPOSITS:

Contact Name: Marilyn MaracicBilling Address: Jones Day, 222 E. 41st StreetNew York, NY 10017-6702Phone: (212) 790-6417 Fax: (212) 869-9741Do you have a current ATCC account number?  Yes  NoIf Yes: ATCC Account Number = 178147If No: To apply for an account with ATCC, please complete a New Account Application located on our Web site ([www.atcc.org](http://www.atcc.org)) and return it with supporting documentation to ATCC for approval.

13. Name, address, phone and fax number of your Attorney of Record.

Geraldine F. Baldwin, Esq.  
Jones Day 222 E 41st Street  
New York, NY 10017-6702 (Ref: Docket or Case No. 11183-013-999)

14. **MUST BE COMPLETED.** Deposited on behalf of. (Verify with your management who owns the deposit. The owner is usually a company or institution, and not an individual.)

MacroGenics, Inc.

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Joseph E. Panigot Joseph E. Panigot 5/4/04  
 Printed Name Signature Date

Address: MacroGenics, Inc., 1500 East Gude Drive, Rockville, MD 20850

Phone: (301) 354-0686 Fax: 301-251-5321 E-mail: panigotj@macrogenics.com

#### SHIPPING INFORMATION

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Fax: (703) 365-2745  
 E-mail: PatentDeposit@atcc.org

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The depositor is ultimately responsible for the shipment of deposits to ATCC and compliance with all applicable government regulations for the packaging and movement of the material. The depositor shall indemnify ATCC, to the extent permitted by law, against claims resulting from the violation of applicable government regulations caused by the depositor's shipment of deposits to ATCC.

#### STORAGE & FEES

Storage: Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

Fees: All fees are subject to change. For current fees and other information, check our Web site at [www.atcc.org](http://www.atcc.org) or request a quotation of fees by e-mail at [PatentDeposit@atcc.org](mailto:PatentDeposit@atcc.org) or fax: (703) 365-2745.

ATCC USE ONLY: ATCC DESIGNATION \_\_\_\_\_ REC'D \_\_\_\_\_ V.T. RESULT \_\_\_\_\_

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 Cell line – the species and tissue of origin, geographical source of isolation, and any known associated hazards (HIV, EBV, etc.)  
 Genetic material – the name of organism from which vector, clone or library is derived, the source of the DNA insert identified by species (e.g., human, mouse) scientific name, the name of gene, and the identity of the host organism  
 Consortia or mixed culture – the identity of each component of the mixture  
 Seeds, embryos, insect eggs, etc. – the common name, the scientific name of the source of the deposit, and geographical source

HYBRIDOMA FERRIA TRANSGENIC MICE WERE IMMUNIZED WITH MAMMALIAN EXPRESSED EXTRACELLULAR PORTION OF THE RIB. LYMPHOCYTES FROM THE IMMUNIZED MICE WERE FUSED WITH H2K1 MYELOMA CELLS TO IMMORTALIZE THEM.

2. Strain designation\* (i.e., number, symbols, etc.). 2E1  
 \*The strain designation must correspond with the vial labels.

3. Is this an original deposit under the Budapest Treaty?  Yes  No

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty?  
 Yes  No  
 If yes, please indicate ATCC designation. \_\_\_\_\_

5. Is this deposit a mixture of microorganisms or cells?  Yes  No  
 If yes, please describe:

6. Provide details necessary to cultivate, test for viability and store the deposit. If a mixture, provide description of components and a method to check for presence. If a plasmid, provide name of host and antibiotic resistance.

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7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).

ADHERENT CELLS

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics?  Yes  No  
 If yes, please list the antibiotics: GENTAMYCIN (sodium)  
 b. If deposit is a hybridoma, what is the isotype of the antibody produced? murine IgG1

8. Safety: Is this strain hazardous to humans? NO Animals? NO Plants? NO

If yes, what is the recommended biosafety level for working with this strain?

(Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. HHS Publication No. (CDC) 93-8395, U.S. Department of Health and Human Services, Centers for Disease Control, Washington, DC; U.S. Government Printing Office, 1999. The entire text is available online at [www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4sec.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4sec.htm))

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If yes, please indicate genus and species and whether wild or captive bred. \_\_\_\_\_

c. Is work performed at your facility with exotic viruses affecting livestock and avian species?  Yes  No

d. Identify any reagents of animal origin used to cultivate this organism/cell line (serum, growth factors, trypsin, etc.) and manufacturer, if known: FETAL BOVINE SERUM CERTIFIED, ORIGIN: UNITED STATES, Mycoplasma, Virus, Bacteriophage and Endotoxin Tested (IN VITROGEN CORPORATION).

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If "yes," please state which countries: \_\_\_\_\_

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## 11. Notification: ATCC will notify you of your ATCC number after viability of the deposit has been confirmed.

Name of individual to notify: Joseph E. Panigot

Fax: 301-251-5301 Phone: 301-354-0688 E-mail: panigotj@macrogenics.com

## 12. Payment by check or credit card (MasterCard, VISA or American Express) must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts purchase orders for the exact amount.

Purchase Order No. \_\_\_\_\_

Check No. \_\_\_\_\_

Credit Card number. \_\_\_\_\_

MasterCard  VISA  American Express

Exp. Date: \_\_\_\_\_

Name shown on card: \_\_\_\_\_ (Please print clearly or type)

Signature of card holder: \_\_\_\_\_

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX FOR ALL DEPOSITS:

Contact Name: Marilyn Maracic

Billing Address: Jones Day, 222 E. 41st Street

New York, NY 10017-6702

Phone: (212) 780-6417 Fax: (212) 869-9741

Do you have a current ATCC account number?  Yes  No

If Yes: ATCC Account Number = 178147

If No: To apply for an account with ATCC, please complete a New Account Application located on our Web site ([www.atcc.org](http://www.atcc.org)) and return it with supporting documentation to ATCC for approval.

13. Name, address, phone and fax number of your Attorney of Record.

Geroldine F. Baldwin, Esq.  
Jones Day, 222 E. 41st Street  
New York, NY 10017-6702 (Ref: Docket or Case No. 111B3-013-999)

14. MUST BE COMPLETED. Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institution, and not an individual.)

MacroGenics, Inc.

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Joseph E. Peniget Joseph E. Peniget 5/14/04  
 Printed Name Signature Date

Address: MacroGenics, Inc., 1500 East Gude Drive, Rockville, MD 20850

Phone: (301) 354-0686 Fax (301) 251-5321 E-mail: penigetj@macrogenics.co.

#### SHIPPING INFORMATION

BEFORE SHIPPING, PLEASE CONTACT THE ATCC PATENT DEPOSITORY FOR SHIPMENT ADVICE:

Fax (703) 365-2745  
 E-mail: [PatentDeposit@atcc.org](mailto:PatentDeposit@atcc.org)

#### SHIPPING NOTICE:

The depositor is ultimately responsible for the shipment of deposits to ATCC and compliance with all applicable government regulations for the packaging and movement of the material. The depositor shall indemnify ATCC, to the extent permitted by law, against claims resulting from the violation of applicable government regulations caused by the depositor's shipment of deposits to ATCC.

#### STORAGE & FEES

Storage: Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

Fees: All fees are subject to change. For current fees and other information, check our Web site at [www.atcc.org](http://www.atcc.org) or request a quotation of fees by e-mail at [PatentDeposit@atcc.org](mailto:PatentDeposit@atcc.org) or fax (703) 365-2745.

ATCC USE ONLY: ATCC DESIGNATION \_\_\_\_\_ REC'D \_\_\_\_\_ V.T. RESULT \_\_\_\_\_

ATCC® is a registered trademark of the American Type Culture Collection.



# BUDAPEST TREATY DEPOSIT FORM (BP/1)

American Type Culture Collection  
P.O. Box 1549  
Manassas, VA 20108

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF A PATENT PROCEDURE

ALL QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED.

1. Name of deposit. Please mark the appropriate box and provide the information requested for the material:

- Microorganism – the complete scientific name including genus and species plus the source of the material
- Virus – the name, whether plant or animal, and source including geographic location
- Cell line – the species and tissue of origin, geographical source of isolation, and any known associated hazards (HIV, EBV, etc.)
- Genetic material – the name of organism from which vector, clone or library is derived, the source of the DNA insert identified by species (e.g., human, mouse) or scientific name, the name of gene, and the identity of the host organism
- Consortia or mixed culture – the identity of each component of the mixture
- Seeds, embryos, insect eggs, etc. – the common name, the scientific name of the source of the deposit, and geographical source

HYBRIDOMA. F<sub>1</sub> RIIA TRANSGENIC MICE WERE IMMUNIZED WITH MAMMALIAN EXPRESSED EXTRACELLULAR PORTION OF F<sub>1</sub> RTB. LYMPHOCYTES FROM THE IMMUNIZED MICE WERE FUSED WITH HL1 MYELOMA CELLS TO IMMORTALIZE THEM.

2. Strain designation\* (i.e., number, symbols, etc.) 249

\*The strain designation must correspond with the vial labels.

3. Is this an original deposit under the Budapest Treaty?  Yes  No

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty?

Yes  No

If yes, please indicate ATCC designation.

5. Is this deposit a mixture of microorganisms or cells?  Yes  No

If yes, please describe:

6. Provide details necessary to cultivate, test for viability and store the deposit. If a mixture, provide description of components and a method to check for presence. If a plasmid, provide name of host and antibiotic resistance.

DMEM MODIFIED EAGLE MEDIUM SUPPLEMENTED WITH 15% FETAL CALF SERUM, 2 mM GLUTAMINE AND 50 µg/ml of GENTAMICIN. CELLS HAVE BEEN FROZEN (10,10<sup>6</sup> CELLS/VIAL) IN FETAL CALF SERUM CONTAINING 10% OF DMSO AND PLACED IN LIQUID NITROGEN.

7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).

ADHERENT CELLS

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics?  Yes  No  
If yes, please list the antibiotics: GENTAMICIN (50 µg/ml)

b. If deposit is a hybridoma, what is the isotype of the antibody produced? mIgG2a

8. Safety: Is this strain hazardous to humans? NO Animals? NO Plants? NO

If yes, what is the recommended biosafety level for working with this strain?

(Refer to *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. HHS Publication No. (CDC) 93-8395. U.S. Department of Health and Human Services, Centers for Disease Control, Washington, DC: U.S. Government Printing Office; 1999. The entire text is available online at [www.cdc.gov/od/ohs/biosafety/bmbl4/bmbl4toc.htm](http://www.cdc.gov/od/ohs/biosafety/bmbl4/bmbl4toc.htm).)

9. Regulatory Compliance:

- a. Was the material derived from a human?  Yes  No  
If yes, was an IRB-approved consent form (human subjects) obtained?  Yes  No
- b. Was this material obtained from wildlife?  Yes  No  
If yes, please indicate genus and species and whether wild or captive bred. \_\_\_\_\_
- c. Is work performed at your facility with exotic viruses affecting livestock and avian species?  Yes  No
- d. Identify any reagents of animal origin used to cultivate this organism/cell line (serum, growth factors, trypsin, etc.) and manufacturer, if known: FETAL BOVINE SERUM CERTIFIED. Origin: United STATES.  
mycoplasma virus, BACTERIOPHAGE & ENDOTOXIN TESTED (INVITROGEN  
COOPERATION)

10. Availability:

Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent Patent Office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered:

- a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued?  Yes  No
- b. As of the date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requesters that satisfy Patent Offices in countries not signatory to the Budapest Treaty?  Yes  No  
If "yes," please state which countries: \_\_\_\_\_

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution. After a U.S. Patent issues and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office (USPTO) Rules and Regulations (37 CFR 1.808 [a][2]).

11. Notification: ATCC will notify you of your ATCC number after viability of the deposit has been confirmed.

Name of individual to notify: Joseph E. Panigot

Fax: 301-351-5321 Phone: 301-354-0696 E-mail: panigotj@macrogenics.com

12. Payment by check or credit card (MasterCard, VISA or American Express) must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts purchase orders for the exact amount.

Purchase Order No. \_\_\_\_\_

Check No. \_\_\_\_\_

Credit Card number. \_\_\_\_\_

MasterCard  VISA  American Express

Exp. Date: \_\_\_\_\_

Name shown on card: \_\_\_\_\_

(Please print clearly or type)

Signature of card holder: \_\_\_\_\_

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX FOR ALL DEPOSITS:

Contact Name: Marilyn Maracic

Billing Address: Jones Day, 222 E. 41st street

New York, NY 10017-6702

Phone: (212) 790-6417

Fax: (212) 869-4741

Do you have a current ATCC account number?  Yes  No

If Yes: ATCC Account Number = 178147

If No: To apply for an account with ATCC, please complete a New Account Application located on our Web site ([www.atcc.org](http://www.atcc.org)) and return it with supporting documentation to ATCC for approval.

13. Name, address, phone and fax number of your Attorney of Record.

Genevieve F. Baldwin, Esq.  
Jones Day 222 E. 41st Street  
New York, NY 10017-6702

(Ref: Docket or Case No. 11183-013-999)

14. **MUST BE COMPLETED.** Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institution, and not an individual.)

MacroGenics, Inc.

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Joseph E. Panigot  
Printed Name

Joseph E. Panigot  
Signature

5/4/06  
Date

Address: MacroGenics, Inc., 1500 East Gude Dr., Rockville, MD 20850

Phone: (301) 354-0666 Fax (301) 251-5321 E-mail: panigot@macrogenics.com

#### SHIPPING INFORMATION

BEFORE SHIPPING, PLEASE CONTACT THE ATCC PATENT DEPOSITORY FOR SHIPMENT ADVICE:

Fax: (703) 365-2745

E-mail: PatentDeposit@atcc.org

#### SHIPPING NOTICE:

The depositor is ultimately responsible for the shipment of deposits to ATCC and compliance with all applicable government regulations for the packaging and movement of the material. The depositor shall indemnify ATCC, to the extent permitted by law, against claims resulting from the violation of applicable government regulations caused by the depositor's shipment of deposits to ATCC.

#### STORAGE & FEES

**Storage:** Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

**Fees:** All fees are subject to change. For current fees and other information, check our Web site at [www.atcc.org](http://www.atcc.org) or request a quotation of fees by e-mail at [PatentDeposit@atcc.org](mailto:PatentDeposit@atcc.org) or fax: (703) 365-2745.

ATCC USE ONLY: ATCC DESIGNATION PTA-5962 REC'D 5/7/04 V.T. RESULT 5/6/04

ATCC

505421-600001

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

**INTERNATIONAL FORM**

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.**

To: (Name and Address of Depositor or Attorney)

MacroGenics, Inc.  
Joseph E. Panigot  
1500 East Gude Drive  
Rockville, MD 20850

Deposited on Behalf of: MacroGenics, Inc.

**Identification Reference by Depositor:**

Hybridoma: 1D5  
Hybridoma: 1F2  
Hybridoma: 2D11  
Hybridoma: 2E1  
Hybridoma: 2H9

**Patent Deposit Designation**

PTA-5958  
PTA-5959  
PTA-5960  
PTA-5961  
PTA-5962

The deposits were accompanied by:    a scientific description, a proposed taxonomic description indicated above. The deposits were received May 7, 2004 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:   X   We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 25, 2004. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris  
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: June 26, 2004

cc: Geraldine F Baldwin, Esq.  
Docket or Case No.: 11183-013-999